

REMARKS

In response to the Office Action mailed April 7, 2004, Applicants request consideration of the following remarks.

Claims 1-29 are pending. These claims cover methods of reducing inflammation or infection of a mucosal membrane. The methods include contacting a problem area of the mucosal membrane with a therapeutically effective amount of one or more antimicrobial metals to provide a localized anti-inflammatory effect. The one or more antimicrobial metals are characterized by sufficient atomic disorder, such that the metal, in contact with an alcohol or water-based electrolyte, releases atoms, ions, molecules, or clusters of at least one antimicrobial metal at a concentration sufficient to provide a localized anti-inflammatory effect

The Examiner rejected claims 1-18 and 25-29 under 35 U.S.C. §103(a) as being unpatentable over the combined teachings of Chemical Abstracts 25:2814A ("Deseniss"), Derwent Abstract 2000-161633 ("Li"), WO 95/13704 (Burrell I) and WO 98/41095 (Burrell II).

Deseniss describes forming a compound by mixing colloidal silver with 7-iodo-8-hydroxyquinoline, and using the compound against tuberculosis. (Declaration of Robert H. Demling under 37 C.F.R. §1.132 ("Demling Declaration") at ¶4. The Demling Declaration is submitted herewith.) Deseniss does not provide proof that the compound was effective against tuberculosis. (*Id.*) However, even assuming that the compound was effective against tuberculosis, the compound contains iodine and hydroxyquinoline, both of which have each been reported to have antimicrobial effects. (*Id.*) Moreover, in general, a compound that is an antimicrobial compound is not also an anti-inflammatory compound. (*Id.*) Thus, assuming that the compound is in fact effective against tuberculosis, one skilled in the art would not conclude from Deseniss that the silver contained in his compound would reduce the inflammation or infection of a mucosal membrane. (*Id.*) As a result, one skilled in the art would not have been motivated by Deseniss to try a different silver-containing composition to reduce the inflammation or infection of a mucosal membrane. (*Id.*)

Li reports on an anti-inflammatory and analgesic liquid medicine for a variety of mucosal disorders from viral and bacterial infections. (*Id.* at ¶5.) The liquid medicine is formed of silver

nitrate and distilled water. (*Id.*) Li does not contain any data to prove the assertion that the liquid medicine was actually effective in treating any of the mucosal disorders. (*Id.*) Without such data, one skilled in the art may have found it difficult to believe that the liquid medicine actually exhibited the reported properties because silver nitrate is known to be toxic when ingested or applied to mucosal membranes. (*Id.*) Even assuming that Li's liquid medicine did exhibit the reported properties, silver nitrate is generally known to exhibit biological activity because of the nitrate ion (which is highly oxidizing), and the silver ion is thought to be just a counterion for the nitrate. (*Id.*) One skilled in the art would see no evidence in Li that the silver contained in his liquid medicine, which was apparently in the form of Ag⁺, would provide the reported properties of the liquid medicine. (*Id.*) Furthermore, in general, a compound that is an antimicrobial compound is not also an anti-inflammatory compound. (*Id.*) As a result, even assuming that the liquid medicine did exhibit the reported properties, one skilled in the art would not conclude from Li that the silver in his liquid medicine would reduce the inflammation or infection of a mucosal membrane. (*Id.*) One skilled in the art therefore would not have been motivated by Li to try a different silver-containing composition to reduce the inflammation or infection of a mucosal membrane. (*Id.*)

Neither Burrell I nor Burrell II cure the infirmities of Deseniss and/or Li because neither Burrell I nor Burrell II disclose or suggest the use of the metals disclosed therein to reduce inflammation or infection of a mucosal membrane.

Neither Deseniss, Li, Burrell I nor Burrell II, alone or in combination, disclose or suggest the methods covered by claims 1-18 and 25-29, and there is no suggestion to combine these references to provide such methods. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 1-18 and 25-29 under 35 U.S.C. §103(a) as being unpatentable over the combined teachings of Deseniss, Li, Burrell I and Burrell II.

The Examiner rejected claims 1-8 and 13-29 under 35 U.S.C. §103(a) as being unpatentable over the combined teachings of Chemical Abstracts 111:127022 ("Yakubov"), Derwent Abstract 1996-186468 ("Zhivoglyadov"), Burrell I and Burrell II.

Yakubov reports on the treatment of herpes using a solution that contains water, ammonia and silver nitrate. (Demling Declaration at ¶6.) Ammonia is known to be a disinfectant. (*Id.*) In addition, in general, a compound that is an antimicrobial compound is not also an anti-inflammatory compound. (*Id.*) As a result, one skilled in the art would not conclude from Yakubov that the silver contained in his solution would reduce the inflammation or infection of a mucosal membrane, and one skilled in the art would not have been motivated by Yakubov to try a different silver-containing composition to reduce the inflammation or infection of a mucosal membrane. (*Id.*)

Zhivoglyadov reports on the topical treatment of gonorrhea using a solution containing colloidal silver and hydrogen peroxide. (*Id.* at ¶7.) Hydrogen peroxide is known to be an antimicrobial agent. (*Id.*) Moreover, in general, a compound that is an antimicrobial compound is not also an anti-inflammatory compound. (*Id.*) Hence, one skilled in the art would not conclude from Zhivoglyadov that the silver contained in his solution would reduce the inflammation or infection of a mucosal membrane, and one skilled in the art would not have been motivated by Zhivoglyadov to try a different silver-containing composition to reduce the inflammation or infection of a mucosal membrane. (*Id.*)

Neither Burrell I nor Burrell II cure the infirmities of Yakubov and/or Zhivoglyadov because neither Burrell I nor Burrell II disclose or suggest the use of the metals disclosed therein to reduce inflammation or infection of a mucosal membrane.

Neither Yakubov, Zhivoglyadov, Burrell I nor Burrell II, alone or in combination, disclose or suggest the methods covered by claims 1-8 and 13-29, and there is no suggestion to combine these references to provide such methods. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 1-8 and 13-29 under 35 U.S.C. §103(a) as being unpatentable over the combined teachings of Yakubov, Zhivoglyadov, Burrell I and Burrell II.

Applicants believe the application is in condition for allowance, which action is requested.

Applicant : Burrell et al
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Enclosed is a Petition for a three month extension of time and a check to cover costs associated with this petition. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 9/28/04



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